The Honorable Ricardo S. Martinez

UNITED STATES DISTRICT COURT FOR THE
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

UNITED STATES OF AMERICA, *ex rel.* Expose Healthcare Fraud, LLP,

Plaintiff,

v.

BIOFRONTERA AG and BIOFRONTERA INC.,

Defendants.

CASE NO. 21-CV-00582-RSM

FILED UNDER SEAL

Noted for Consideration on:
February 7, 2024

UNITED STATES' *EX PARTE* APPLICATION FOR AN EXTENSION OF TIME TO CONSIDER ELECTION TO INTERVENE

Pursuant to the False Claims Act, 31 U.S.C. §§ 3729–33 ("FCA"), the United States of America respectfully applies to the Court *ex parte* for an Order extending for six months, until and including August 12, 2024, the period during which this case will remain under seal to allow the United States additional time to determine whether to intervene in this action. Relator's counsel has been consulted and concurs with this request.

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PROCEDURAL HISTORY

On or about April 28, 2021, Relator Expose Healthcare Fraud, LLP filed a Complaint in this action under the *qui tam* provisions of the FCA, which permit individuals to file actions on behalf of the United States. Relator completed service on the United States on or about June 11, 2021. Following service of a *qui tam* action, the FCA affords an initial sixty-day period within which the action remains under seal and during which the United States may investigate Relator's allegations and reach a decision regarding whether to intervene in the action. *See* 31 U.S.C. §§ 3730(a), (b)(2). The FCA also expressly contemplates that the government's initial sixty-day investigative period may be extended more than once upon a showing by the United States of "good cause." *Id.* § 3730(b)(3). This is the government's sixth request for an extension of the seal in this matter. The current deadline for an intervention decision is February 12, 2024.

RELATOR'S ALLEGATIONS

According to the Complaint, Defendants Biofrontera AG and Biofrontera, Inc. (collectively, "Biofrontera") are related pharmaceutical companies. Biofrontera AG has its headquarters in Leverkusen, Germany and Biofrontera, Inc. is an American subsidiary incorporated in Delaware. Biofrontera manufactures and markets Ameluz, a topical prescription medication used to treat actinic keratoses of the face and scalp. Actinic keratoses, if left untreated, can lead to cancer. Ameluz began being sold in the United States in 2016. Relator is an LLC incorporated in Delaware whose sole member worked as Biofrontera's territorial sales manager for Virginia, Maryland, and Washington D.C. from January 2018 until June 2020.

As this Court is aware, Relator alleges that Defendants knowingly submitted or caused to be submitted false or fraudulent claims to the United States that resulted from violations of the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b). Relator also alleges that Defendants marketed

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Ameluz for "off-label" use—i.e., uses not specifically approved by the United States Food and Drug Administration. While the FDA allows physicians to prescribe medications for off-label uses, Federal healthcare programs often restrict or preclude coverage for unapproved uses. The FDA has approved Ameluz only for use while applied to the skin as a part of photodynamic therapy with a BF-RhodoLED red-light lamp. The red-light lamp is a product that physicians in the United States would need to purchase separately, at significant cost. Instead, Relator alleges that Defendants knowingly promoted and encouraged the application of Ameluz with blue-light lamps, which, unlike red-light lamps, were already in use in specialty clinics in the United States for actinic keratosis treatment in conjunction with a competing medication. In addition, Relator alleges that Defendants instructed physicians that they could utilize a shorter (and less clinically effective) incubation period than the FDA-approved three-hour incubation period. Relator alleges that Defendants induced physicians to prescribe Ameluz for these non-covered off-label uses, including for beneficiaries of Federal healthcare programs, in violation of the FCA.

Relator also alleges that Defendants violated the AKS by creating a program to provide physicians with free "training tubes" of Ameluz sample products along with paid orders of Ameluz. Relator alleges that, instead of being used for training purposes, these free tubes were a kickback that physicians would then use to treat patients and be reimbursed for by Federal healthcare programs and other payors, even though the physicians had not actually paid for the prescriptions up front, contrary to Medicare's "buy and bill" reimbursement model. For each order of ten tubes of Ameluz, Relator alleges that Defendants would provide two additional tubes for free, which physicians could then bill for at the Medicare reimbursement rate of $318 per tube. Physicians who placed even larger orders were rewarded with additional training tubes, e.g., five free tubes for a twenty-tube order. Relator also alleges that Defendants would reimburse physicians for Ameluz tubes if Medicare or

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another insurance provider denied reimbursement for any reason. Relator alleges that Defendants facilitated these training tube payments and reimbursements in order to induce the prescribing of Ameluz over a competing treatment. Because older Americans who have reached Medicare's eligibility age are disproportionately affected by actinic keratoses, Medicare, through Medicare Part B and Medicare Advantage, is one of the most significant payors for Ameluz in the United States.

THE INVESTIGATION

As this Court knows, on May 27, 2022, the United States issued a Civil Investigative Demand to Biofrontera, Inc., requesting documents and information relating primarily to Relator's AKS allegations. Since the last extension of the seal in this matter, Defendants have made three productions of documents, including over 15,400 pages of documents. Defendants have, in total, made eleven productions consisting of over 55,000 pages of documents, and have now indicated that they have completed their production, pending any government requests for additional documents or information. The United States has been working diligently to review the documents produced to date. If the Court grants an extension of the seal, the United States will use the extension to hopefully complete their review of the produced documents and information and review any newly-produced documents and information. The United States may also use the extension to contact former employees and other witnesses, if warranted.

The extension sought in this Application is necessary to permit the United States to further investigate Relator's allegations by continuing to conduct extensive claims analyses and by potentially interviewing additional witnesses and issuing subpoenas and/or CIDs. As noted at the outset, Relator's counsel has been consulted and has no objection to this request for additional time.

ARGUMENT AND AUTHORITIES

The FCA expressly contemplates the United States obtaining extensions of time to make its

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intervention decision in *qui tam* actions. *See* 31 U.S.C. § 3730 (b)(3) (the United States "may, for good cause shown, move the court for extensions of time . . . ."). For the reasons set forth above, the government contends that the "good cause" standard is satisfied in this case.

The U.S. Judicial Conference (the "Conference") has recognized and accepted that it may take the government several years to complete an FCA investigation. In 2015, the Conference amended the reporting requirements of the Civil Justice Reform Act for cases on the "three-year list." The amendment changed the pending date for qui tam cases from the original filing date to the date the case is unsealed. Of significance, in considering the justification for the proposed amendment, the Conference noted that the investigative and intervention process in FCA qui tam cases "can be lengthy." See "Report of the Proceedings of the Judicial Conference of the United States," at 10–11 (March 10, 2015).

The United States also respectfully requests that the Court order that the Complaint and other filings be kept under seal through August 12, 2024, unless otherwise ordered by the Court. Such an extension of the seal is contemplated by, and consistent with, the express terms of the FCA. *See* 31 U.S.C. § 3730(b)(3). Experience demonstrates that concluding a non-judicial resolution of this matter, should the facts so warrant, will be facilitated if Relator's allegations have not yet been publicly disseminated.

CONCLUSION

The United States requests that the Court enter an Order extending for six months, until and including August 12, 2024, the period during which this case will remain under seal to allow the United States additional time to make an intervention decision in this action.\

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DATED this 7th day of February, 2024.

Respectfully submitted,

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I certify that this memorandum contains 1,282 words, in compliance with the Local Civil Rules.